

**EXHIBIT 2**

**NidaCon International AB**

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Contact: Paul V. Holmes *MSc, PhD, DrMedSc.*, General Manager

July 5, 2001

**510(k) Summary of Safety and Effectiveness**

1. Identification of the Device:  
Proprietary-Trade Name: *NidOil™*  
Classification Name/Product Code: Reproductive Media and Supplements (21 CFR 884.6180) Procode: 85 MQL  
Common/Usual Name: Assisted Reproduction Media
2. Equivalent legally marketed devices: **Ovoil™ 150, K991351**
3. Indications for Use (intended use) The product is intended for use as an oil overlay during gamete and embryo culture for ART, (Assisted Reproduction Technology) and during manipulations outside the incubator.
4. Description of the Device: *NidOil™* is a light, highly purified, paraffin oil product to be used as an overlay for gamete and embryo culture in the incubator, and for manipulations outside the incubator.  
Shelf life of two years from production date in unopened bottle  
Spec. density of 0.82 - 0.87 g/cm<sup>3</sup>;  
Dynamic viscosity (20 °C) 25.0 - 80.0 mPas  
Cinematic viscosity (40 °C) ≤ 33.5 mm<sup>2</sup>/s  
MEA tested  
Sterilized by filtration during aseptic filling  
Packaged in amber borosilicate glass bottles with silicone stoppers and Tamper-proof seals  
Storage of unopened bottles at ambient temperature  
Opened bottles can also be stored at ambient temperature, if opened only under sterile conditions.  
*NidOil™* is CE marked in countries of the European Union. It is supplied in 100 and 250 ml bottles.

5. Safety and Effectiveness, comparison to predicate devices. The results of clinical trials and comparative testing against predicate product indicates that the new device is as safe and effective as the predicate device. The intended use of the product is the same.
6. Conclusion: Based on the similarity of composition, product testing results, and intended use, *NidOil™* is substantially equivalent to the predicate device named above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 3 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NidaCon International AB  
c/o Mr. Daniel Kamm  
Regulatory Engineer  
Kamm & Associates  
P.O. Box 7007  
DEERFIELD IL 60015

Re: K012123  
NidOil™  
Dated: July 5, 2001  
Received: July 6, 2001  
Regulatory Class: II  
21 CFR §884.6180/Procode: 85 MQL

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

**j) Indications for Use**

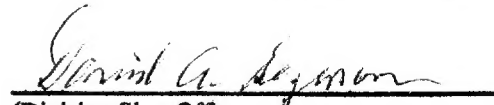
510(k) Number K012123

**Device Name:** *NidOil™*

**Indications for Use:** The product is intended for use as an oil overlay during gamete and embryo culture for ART, (Assisted Reproduction Technology) and during manipulations outside the incubator.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over the Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K012123